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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,538	03/20/2001	Mary A. Reppy	2001/00005	9053

7590

03/22/2002

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/811,538

Applicant(s)

REPPY ET AL.

Examiner

My-Chau T. Tran

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 20-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 9-11, 15, 16, 18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1641

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-19 of Group I, in Paper No. 4 is acknowledged.
2. Claims 20-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

4. The listing of references in the specification on pages 2, 4, 10, 14, and 17 is **not** a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

5. Claims 9-10, 15-16, and 18-19 are objected to because of the following informalities:

It is unclear whether there are any missing parts from the large blank space on page 38 (between claim 9 and 10), page 39 (between claim 15 and 16), and page 40 (between claim 18 and 19). Appropriate correction is required.

6. Claim 11 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) It is indefinite in the use of the term “incorporated” in claim 1 since it is unclear how the substrate is “incorporated” in the array. Is the substrate the base of the array or the array itself?

Art Unit: 1641

- b) The phrase “direct affinity” of claim 1 renders the claim indefinite since it does not particularly point out what type of “direct affinity” this is. Is it recognition? Attachment? Or blocking? A “direct affinity” can refer to two pieces of a magnet, which is not supported by the specification.
- c) In claim 1 the terms “can function” and “can react” are vague and indefinite. It is unclear if the substrate actually does what it is claimed.
- d) It is unclear what is meant by the term “binder” of claim 1. A “binder” can refer to a cord or tie, which is not supported by the specification.
- e) Claim 1 is indefinite for the reason that there are no recited or required method steps, which would cause a “change in fluorescence”. Additionally, it is unclear what entity is undergoing the “change in fluorescence”. There is no requirement that the “array” itself be fluorescent.
- f) In claim 1, it is unclear what is meant by the term “a three-dimensional array”. As shown in figure 1, a “polydiacetylene backbone” is by its very nature “three-dimensional”. Claim 1, as written reads on a “polydiacetylene” in any form including a simple film.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1641

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al. (US Patent 5,415,999) in view of Charych et al. (US Patent 6,180,135 B1).

Saul et al. disclosed a method for detection of an analyte in a sample (Abstract). The method comprises the use of a polydiacetylene backbone (col. 2, line 61-67; claim 1 and 6). A substrate incorporated is in an array (col. 3, line 10-15). The substrate has direct affinity for the analyte or can function as a binder to the analyte or can react with the analyte (claim 1(a), col. 14, line 21-32; col. 3, line 34-39). Detecting the change in fluorescence is used to indicate the

Art Unit: 1641

presence of the analyte (col. 3, line 25-29; claim 1(b), line 32-33). The analyte is an enzyme, antigen, antibody or antibody fragment and the substrate is a specific binding pair member of the analyte (col. 2, line 44-47; col. 6, line 9-21, and 67-68 and continue to col. 7, line 1-6; col. 10, line 5-24). The substrate includes a ligand (col. 3, line 34-35 and 40-42). The substrate includes a reactive substrate (col. 6, line 9-14). The polydiacetylene of the array exhibits fluorescence and the fluorescence increases as an indication of the presence of the analyte (col. 8, line 18-28).

The method of Saul et al. differs from the claimed invention in failing to disclose a three-dimensional array of a polydiacetylene backbone and the array is in the form of liposomes or tubules.

Charych et al. disclosed a method for detection of an analyte in a sample comprising a three-dimensional array of a polydiacetylene backbone and the array is in the form of liposomes or tubules (Abstract; col. 4, line 24-33; col. 8, line 63-64). The liposomes produced by either of the process of claim 1 or 22 of Charych et al. are the same as those of instant claim 1 with the exception that the array of the instant claim is fluorescent in nature while that of Charych et al. is colorimetric in nature.

In view of Charych et al, teaching that ~~both colorimetric and fluorescent~~ detection methods are well known for use with analytical methods which use polydiacetylene films (col. 2, line 59 through col. 3, line 6) it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the *fluorescent* method of Saul et al. by including a three-dimensional array of a *colorimetric* polydiacetylene backbone in an array in the form of liposomes or tubules as taught by Charych et al. with the expectation of obtaining an equivalent method of direct detection of small molecules using a three dimensional polymeric assemblies

Art Unit: 1641

and a test system that can be suspended in fluid or bound to various supports (Charych et al., col. 3, line 29-39). Criticality has not been demonstrated for the use of fluorescent rather than colorimetric polydiacetylene backbones in the method of Charych et al.

The features of the dependent claims are either specifically described by the reference (e.g. fluorophore monitoring) or constitute obvious variations in parameters which are routinely modified in the art (e.g. wavelength detection or background detection) and which have not been described as critical to the practice of the invention.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following prior art teaches the state of the art: Ribí et al. (US Patent 5,427,915), Charych et al. (US Patent 6,022,748), and Saul et al. (US Patent 5,618,735).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999.

The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Application/Control Number: 09/811,538

Page 8

Art Unit: 1641

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct

March 21, 2002

Mary E. Ceperley
MARY E. CEPERLEY
PRIMARY EXAMINER
AU 1641